EXHIBIT H

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Ronald C. Lundquist and David A. Walters	Examiner:	G. Benzion
Serial No.:	07/508,045	Art Unit:	1804
Filed:	April 11, 1990	M&G:	9696.3-US-01
For:	FERTILE TRANSGENIC CORN PLANTS		

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 CFR §1.132

Sir:

I, David A. Somers, declare and say as follows:

1. I received a B.S. degree in Soil Science from the University of Maine in 1974, and M.S. and Ph.D. degrees in Agronomy from Washington State University in 1977 and 1983, respectively. After postdoctoral work at the University of Nottingham, England in 1983-84, I joined the University of Minnesota, Minneapolis, Minnesota in 1984, where I am currently an Associate Professor of Agronomy. I am a member of the American Society of Agronomy, the Crop Science Society of America, the American Society of Plant Physiologists and the Maize Genetics Corporation. I have authored or co-authored more than 40 articles, book chapters and proceedings, primarily in the area of plant physiology, including corn tissue and cell culture,

genetics, herbicide resistance and enzymology, including R.L. Phillips, D.A. Somers and K.A. Hibberd, "Cell/Tissue Culture and In Vitro Manipulation," in Corn and Corn Improvement, G.F. Sprague and J.S. Dudley, eds., ASA, Inc. Madison, WI (1988) at pages 345-387, a book chapter cited by the Examiner against the pending claims.

2. I have read, and am thoroughly familiar with, the above-identified application, with the Office Action dated March 5, 1992, including the cited publications, and with the Amendment filed herewith, and make this declaration in support of the patentability of the claims of the application. I have no direct or indirect financial interest in the application.

3. As evidence of the long-felt need for transgenic maize, the Examiner is requested to consider pages 211-212 of the article by Professor Winston J. Brill, entitled "Agricultural Microbiology" (Scientific American, 199 (September 1981)). In this article, Professor Brill notes the inability of A. tumefaciens to infect cereals, and discusses needs such as nitrogen fixation and enhanced protein quality that could be met by the transfer of foreign genes into cereals.

4. One technique which initially showed promise as a method to introduce DNA directly into intact plant cells was the "particle gun" developed by T.M. Klein et al. in the mid-1980s (for example, see T.M. Klein et al., Nature, 327, 70 (1987)). However, as late as June of 1990, researchers regarded as authorities in the area of field crop transformation expressed their

skepticism that particle acceleration would ever yield stably transformed maize.

5. For example, Dr. Ingro Potrykus, in a review article published after the filing date of the present application (Bio/Technology, 535 (June 1990)) cites the work of Klein et al. and the McCabe et al. paper. Although Potrykus discusses the apparent advantages of biolistics, he is left to ask "[w]hy then with all these advantages have no transgenic cereals been produced . . . we must assume that there are inherent problems." Dr. Potrykus continues to discuss the serious difficulties associated with genetic engineering of monocots:

> . . . my personal experience in working towards the genetic engineering of cereals for the last 18 years convinces me that we still have serious problems in front of us . . .. It seems to me that we are really not yet close to such a situation.

(Page 535, col. 1-2.)

At page 542 in the same article, Potrykus ascribes part of this lack of optimism to his belief that monocot meristematic cells cannot be transformed:

> [A]ccumulated experience of gene transfer experiments with plants is in agreement with the hypothesis that meristematic (embryonic) cells cannot be transformed. I do not know of any experiment that would disprove this hypothesis.

(Page 542, col. 1.)

6. A similar pessimism also pervades his 1990 Physiologia Plantarum review article (Vol. 79, page 125):

> Despite intensive efforts with perfect embryogenic suspensions and scutellum cultures of maize and other cereals, so far there is not a single transgenic cereal seedling. The success with soybean seedlings is probably based on very intimate experience with a well established and efficient system of multiple shoot regeneration from the shoot apex. The different geometry of cereal seedlings together with different responses in shoot meristem culture do not make it easy to apply a similar strategy to cereals. It might well be that the reason for the failure to regenerate transgenic cereals after particle bombardment of either embryogenic suspension or immature scutelli has its cause in the limited amount of DNA carried into the cell by the particles or in the inefficiency with which this DNA dissociates from the particles.

7. An article from the journal Science, 249, 630 (August 10, 1990) published shortly after the announcement that fertile transgenic corn had been achieved, emphasizes the long-felt but unresolved need, as well as the failure of others such as Carol A. Rhodes ("Corn Transformed"). The article begins by noting that the achievement of fertile, transgenic corn is "the capstone of almost a decade's efforts to genetically engineering this country's most important crop," and then continues by noting the "years of frustration" and a renewed effort to genetically engineer corn begun by Carol A. Rhodes and her colleagues. The article notes that while Dr. Rhodes and her group were successful

in regenerating transformed corn, their "celebrations were short-lived: the resulting plants were infertile."

8. The Science article then refers to attempts by the CIBA-Geigy group, who were said to have achieved the regeneration of non-transgenic corn cells into fertile plants. However, it is pointed out that "these techniques, so far, have not worked with genetically transformed corn."

9. In the March 1990 issue of Genetic Engineering News, an article reporting the successful transformation of corn by BioTechnica, quotes Ralph Hardy, president of the Boyce Thompson Institute for Plant Research at Cornell University as follows:

> "Useful corn transformation with the production of fertile plants that transmit the gene to succeeding generations has been an insurmountable roadblock for agricultural biotechnology."

10. The Examiner is also requested to consider the following summary of the art of maize transformation in 1990, published by Timothy Nelson, of the Department of Biology, Yale Unviersity, in The Plant Cell, 2, 589 (July 1990):

> The great experimental advantages of maize for the study of development and genetics have attracted many researchers and have resulted in a huge resource of mapped genes, molecular probes, chromosomal rearrangements, and other tools (citation omitted). It has been a source of frustration to the same researchers that maize has not proved as easy to stably transform as many plants without as

> rich a scientific background. For many dicotyledonous plants, the Agrobacterium-mediated construction of transgenic plants has become a routine and reliable experimental tool. Although this system may be adaptable to the monocot rice (citation omitted), there are no reports of success with maize.

11. In my opinion, these reports accurately reflect the state of the art of *in vitro* corn transformation as of early 1990. At this time, one of skill in the art would have been aware of at least a decade of reports of failures using every available technology to solve a problem of great commercial and humanitarian importance. These reports both demonstrate the lingering skepticism in the art with respect to the possibility of success using any known method to deliver DNA into any maize tissue source, and the acclaim with which the art greeted Applicants' successful preparation of fertile transgenic maize.

12. Copies of all the newly cited publications are attached, and are incorporated by reference herein.

13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statement may jeopardize the validity of the application or any patent issuing thereon.

Date 6/9/92

David A. Somers